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**TO** : Commissioner for Patents
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**FROM** : Oleg F. Kaplun, Esq. of Fay Kaplun & Marcin, LLP

**DATE** : March 13, 2007

**SUBJECT** : U.S. Patent Appln. Serial No. 10/762,715
for *Valved Catheter to Bypass Connector*
Inventor(s): DiMatteo et al.
Our Ref.: 10123/03601

**NUMBER OF PAGES INCLUDING COVER :** 18

**MESSAGE:**

Please see attached.

Thank you.

Attorney Docket No. 10123/03601 (03-225)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**



| | | |
|---|---|---|
| Applicant | : | DiMatteo et al. |
| Serial No. | : | 10/762,715 |
| Filed | : | January 22, 2004 |
| For | : | Valved Catheter to Bypass Connector |
| Group Art Unit | : | 3767 |
| Examiner | : | Phillip Gray |
| Confirmation No. | : | 5203 |

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By: Oleg F. Kaplun (Reg. No. 45,559) Date: March 13, 2007

**TRANSMITTAL**

In support of the Notice of Appeal filed January 2, 2007, transmitted herewith please an Appeal Brief for filing in the above-identified application. Applicants hereby request a one (1) month extension of time. Please charge the Credit card of Fay Kaplun & Marcin, LLP in the amount of $620.00 for the extension fee and filing fees (PTO Form 2038 is enclosed herewith). The Commissioner is hereby authorized to charge the **Deposit Account of Fay Kaplun & Marcin, LLP NO. 50-1492** for additional required fees. A copy of the paper is enclosed for that purpose.

Respectfully submitted,

Dated: March 13, 2007

By: _____
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Attorney Docket No. 10123/03601 (03-225)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**



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PATENT
Attorney Docket No.: 10123/03601

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**
**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**



| | |
|---|---|
| In re Application of: | |
| **DiMatteo et al.** | |
| Serial No.: 10/762,715 | Group Art Unit: 3767 |
| Filed: January 22, 2004 | Examiner: Phillip Gray |
| For: VALVED CATHETER TO BYPASS CONNECTOR | **Board of Patent Appeals and Interferences** |

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Alexandria, VA 22313-1450

## APPEAL BRIEF UNDER 37 C.F.R. § 41.37

In support of the Notice of Appeal filed January 9, 2007, and pursuant to 37 C.F.R. § 41.37, Appellants present their appeal brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 1-5, 7-19, and 21-24 in the final Office Action dated September 29, 2006. The appealed claims are set forth in the attached Claims Appendix.

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02 FC:1251 120.00 OP

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1. Real Party in Interest

This application is assigned to Boston Scientific Scimed, Inc., the real party in interest.

2. Related Appeals and Interferences

There are no other appeals or interferences which would directly affect, be directly affected by, or have a bearing on the instant appeal.

3. Status of the Claims

Claims 1-5, 7-19, and 21-24 stand rejected in the Final Office Action. The final rejection of claims 1-5, 7-19, and 21-24 is being appealed.

4. Status of Amendments

All amendments submitted by the Appellants have been entered.

5. Summary of Claimed Subject Matter

The present invention describes, as recited in independent claim 1, a connector for injecting fluid to a catheter. The connector (100) comprises an attachment portion (104) adapted to fluidly couple to a source of pressurized fluid. (See Specification, p. 6, ll. 14-28; Fig. 1). The connector comprises a bypass element (*e.g.*, 108) fluidly connected to the attachment portion. (See Id., p. 7, l. 1 - p. 8, l. 3; Figs. 1-2). The bypass element is adapted to open a valve of the catheter to permit fluid to flow into the catheter without impinging on the valve. (See Id.). The

connector comprises an overpressure control element (*e.g.*, 306) adapted to maintain a pressure of fluid within the connector below a predetermined threshold level. (See Id., p. 9, ll. 7-16; Fig. 1).

The present invention describes, in an independent claim 18, a fluid coupler. The coupler (100) comprises an elongated tube (102) extending between a first end (104) adapted for fluid connection to a power injector and a second end adapted for fluid connection (via extensions 106) to a catheter (200) including a valve (202) in a proximal part thereof. (See Id., p. 6, ll. 14-28; p. 7, l. 22 - p. 8, l. 3; Figs. 1-2). The second end is insertable into the catheter beyond the valve thereof so that fluid passes through the fluid coupler into the catheter to a distal end thereof without passing through the valve. (See Id.). The coupler comprises a pressure control element (306) adapted to limit a fluid pressure within the coupler to a predetermined threshold level. (See Id., p. 9, ll. 7-16; Fig. 1).

6. Grounds of Rejection to be Reviewed on Appeal

I. Whether claims 1-5, 7-19, and 21-24 are unpatentable under 35 U.S.C. § 103(a) over U.S. Pat. No. 4,142,525 to Binard et al. ("Binard") on view of U.S. Pat. No. 5,227,200 to Crump et al. ("Crump").

7. Argument

I. The Rejection of Claims 1-5, 7-19, and 21-24 Under 35 U.S.C. § 103(a) as Unpatentable Over U.S. Pat. No. 4,142,525 to Binard et al. In view of U.S. Pat. No. 5,227,200 to Crump et al. Should Be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 1-5, 7-19, and 21-24 were rejected under 35 U.S.C. 103(a) as unpatentable over Binard in view of Crump. (See 9/29/06 Office Action, p. 3, ll. 4-6).

Binard describes a syringe assembly that comprises a chamber for retaining fluid, a plunger to pump fluid out of the chamber, and a means for limiting the amount of pressure generated by the syringe during pumping of the fluid. (See Binard, Abstract). Binard includes an extension that has a passageway that communicates with the syringe chamber and the hollow needle. (See Id., col. 3, ll. 26-28). The passageway has a flexible balloon that communicates with the passageway so that it inflates when a predetermined pressure has been reached in the passageway or chamber of the syringe. (See Id., col. 3, ll. 40-44). The balloon serves to limit the amount of pressure generated by the syringe, and prevents ejection of further fluid in the needle and sub-dural space after the predetermined pressure has been attainted. (See Id., col. 4, ll. 6-10). In other words, Binard discloses an overpressure control element that alleviates increases in pressure of fluid by determining if the pressure of the passageway has risen *above* a threshold level.

Crump describes a device used for suction. The respiratory suction apparatus catheter includes a manifold for attachment to the distal hub of an endotracheal tube to form a ventilation circuit, a catheter tube which is displaceable through the manifold and into the endotracheal tube to suction secretions from the tube and lungs, and a valve mechanism disposed adjacent the ventilation circuit to minimize the draw of air from the ventilation circuit of a patient while the catheter is being cleaned. (See Crump, abstract). Specifically, Crump discloses a "respiratory suction catheter apparatus [that] includes a manifold 404 and a catheter 408 which is movable through the manifold to suction secretions from a patient's lungs." (See Crump, col. 11, lines 8-11). Thus, a negative pressure is generated in order to operate the device in Crump.

B. Binard in View of Crump Does Not Disclose or Suggest a Bypass Element Adapted to Open a Valve of the Catheter to Permit Fluid to Flow into the Catheter without Impinging on the Valve, as Recited in Claim 1.

Claim 1 recites a connector for injecting fluid to a catheter, comprising a "bypass element fluidly connected to the attachment portion, the bypass element being adapted to open a *valve of the catheter* to permit fluid to flow into the catheter without impinging on the valve" in combination with "an overpressure control element adapted to maintain a pressure of fluid within the connector below a predetermined threshold level."

In the final rejection, the Examiner correctly stated that Binard does not disclose the valve type that permits fluid to flow into the catheter without impinging the valve. (See 9/29/06 Office Action, p. 4, ll. 8-9). Specifically, Binard does not disclose a "bypass element

adapted to open a *valve of the catheter* to permit fluid to flow into the catheter without impinging on the valve," as recited in claim 1. The Examiner attempted to cure this deficiency with Crump. However, it is respectfully submitted that because the valve disclosed in Crump is not part of the catheter but exists as a separate unit, the Examiner's claim is unfounded.

Appellants respectfully submit that Crump is directed to a mechanism for cleaning the tip of a catheter and that the catheter of Crump includes no valve. (See Crump, col. 1, ll. 12-20). Specifically, the valve 424 cited by the Examiner is located in a manifold which is received around the catheter 408 and no valve is located in the catheter 408. (See Id., col. 11, ll. 18-24; Figs. 5A-C). The manifold 404 shown in Figs. 5A-C includes a port 412d which receives a connector or adaptor 420 into which the catheter 408 is inserted. The valve 424 extends across the opening of the adaptor 420 and is forced open as the catheter 408 is inserted therethrough and which closes when the catheter 408 is withdrawn. (See Id., col. 11, ll. 11-23). Crump explicitly states that the "valve 424 is attached to the adaptor 420 by a flexible base 428," not that the valve is located in or attached to the catheter 408 in any way. (See Id., col. 11, ll. 23-24).

The Examiner asserted that Binard in view of Crump teaches a valve of a catheter which is opened to permit fluid to flow into the catheter. (See 12/4/06 Advisory Action, p. 2, ll. 15-17). Specifically, the Examiner stated that this assertion was based on the premise that a claim limitation is given the broadest interpretation during examination. However, Appellants respectfully submit that even given the broadest interpretation, Crump does not teach a "*valve of the catheter* is opened to permit fluid to flow into the catheter," as recited in claim 1. As

discussed above, the valve 424 of Crump is part of the manifold. The valve 424 is described with great detail in that it creates a seal with an outer circumference of the catheter 408. The created seal is a feature of the valve since a minimized space between the valve and the catheter is desired in Crump. (See Crump, col. 8, ll. 3-5; col. 11, ll. 35-38). Because Crump is directed toward cleaning the catheter prior to removal, Crump focuses on the outer circumference of the catheter 408. Furthermore, there is no disclosure in the entirety of Crump that a valve is located in or part of the catheter 408. A valve located in the catheter 408 defeats one of the features of Crump. Specifically, Crump utilizes *lateral* apertures 248 on the distal end of the catheter 408. Those skilled in the art will understand that a valve located in the catheter 408 of Crump would serve absolutely no purpose and would not benefit the respiratory suction catheter apparatus. Therefore, it is respectfully submitted that Binard and Crump, taken either alone or in combination, do not disclose or suggest a bypass element "adapted to open a *valve of the catheter* to permit fluid to flow into the catheter without impinging on the valve," as recited in claim 1.

Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 103(a) of claim 1 and claims 2-5 and 7-17 which depend directly or indirectly therefrom.

Claim 18 also includes limitations that distinguish over Binard in view of Crump in a manner substantially similar to the reasons stated above in regard to claim 1. Specifically, claim 18 recites "an elongated tube extending between a first end adapted for fluid connection to a power injector and a second end adapted for fluid connection to *a catheter including a valve in*

*a proximal part thereof, the second end being insertable into the catheter beyond the valve thereof* so that fluid passes through the fluid coupler into the catheter to a distal end thereof without passing through the valve." Thus, claim 18 recites a device for insertion into a catheter to open a valve in the catheter and it is respectfully submitted that neither Binard nor Crump either shows or suggests such an arrangement.

Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 103(a) of claim 18 and claims 19 and 21-24 which depend therefrom.

8. Conclusions

For the reasons set forth above, Appellants respectfully request that the Board reverse the final rejections of the claims by the Examiner under 35 U.S.C.§ 103(a) and indicate that claims 1-5, 7-19, and 21-24 are allowable.

Respectfully submitted,

Date: March 13, 2007

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Serial No.: 10/762,715
Group Art Unit: 3767
Attorney Docket No.: 10123/03601



## CLAIMS APPENDIX

1. (Rejected) A connector for injecting fluid to a catheter, comprising:

an attachment portion adapted to fluidly couple to a source of pressurized fluid;

a bypass element fluidly connected to the attachment portion, the bypass element being adapted to open a valve of the catheter to permit fluid to flow into the catheter without impinging on the valve; and

an overpressure control element adapted to maintain a pressure of fluid within the connector below a predetermined threshold level.

2. (Rejected) The connector according to claim 1, wherein the bypass element comprises an elongated tubular component insertable into the catheter through the valve of the catheter.

3. (Rejected) The connector according to claim 2, wherein the elongated tubular component has a diameter selected to fit in a flow opening of the valve of the catheter.

4. (Rejected) The connector according to claim 2, wherein the elongated tubular component is hypotube.

5. (Rejected) The connector according to claim 2, wherein the elongated tubular component includes an outlet which, when the elongated tubular component is inserted into the catheter through the valve, is located distally of the valve.

7. (Rejected) The connector according to claim 1, wherein the overpressure control element comprises a pressure relief valve.

8. (Rejected) The connector according to claim 1, wherein the overpressure control element comprises a controlled failure element designed to fail when a fluid pressure therein reaches the threshold level.

9. (Rejected) The connector according to claim 8, wherein the controlled failure element is an extension tube.

10. (Rejected) The connector according to claim 1, further comprising an external collection jacket disposed around the overpressure control element.

11. (Rejected) The connector according to claim 1, wherein the bypass element is adapted to open a pressure actuated safety valve of a venous catheter.

12. (Rejected) The connector according to claim 1, wherein the attachment portion is adapted to connect to a contrast media power injection system.

13. (Rejected) The connector according to claim 1, wherein the threshold level is selected to be less than a burst pressure of a catheter with which the connector is to be used.

14. (Rejected) The connector according to claim 13, wherein the threshold level is approximately 300 psi.

15. (Rejected) The connector according to claim 14, wherein the threshold level is approximately 100 psi.

16. (Rejected) The connector according to claim 13, wherein the threshold level is approximately 80 psi.

17. (Rejected) The connector according to claim 16, wherein the threshold level is approximately 40 psi.

18. (Rejected) A fluid coupler comprising:

an elongated tube extending between a first end adapted for fluid connection to a power injector and a second end adapted for fluid connection to a catheter including a valve in a proximal part thereof, the second end being insertable into the catheter beyond the valve thereof so that fluid passes through the fluid coupler into the catheter to a distal end thereof without passing through the valve; and

a pressure control element adapted to limit a fluid pressure within the coupler to a predetermined threshold level.

19. (Rejected) The coupler according to claim 18, wherein the elongated tube is a hypotube.

21. (Rejected) The coupler according to claim 18, wherein the pressure control element comprises a section having a burst pressure lower than a burst pressure of the catheter.

22. (Rejected) The coupler according to claim 18, wherein the pressure control element comprises an extension tube connected to the first end.

23. (Rejected) The coupler according to claim 18, wherein the pressure control element comprises a pressure relief valve.

24. (Rejected) The coupler according to claim 18, further comprising a fluid collection jacket surrounding the pressure control element.

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## EVIDENCE APPENDIX

No evidence has been entered or relied upon in the present appeal.

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## RELATED PROCEEDING APPENDIX

No decisions have been rendered regarding the present appeal or any proceedings related thereto.